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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,339	01/28/2004	Edmund Hoppe	DEAV2003/0005 US NP	3296
5487 7590 01/30/2007 ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/766,339	Applicant(s) HOPPE ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,10,12-14,18,19,26-28,32 and 33 is/are allowed.
- 6) ☒ Claim(s) 3-9,11,15-17,20,22-25,29-31,34 and 35 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/1/04</u> | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I in the reply filed on November 2006 is acknowledged. Applicants' arguments were found persuasive, and thus all claims have been rejoined and are under examination.

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1, 2, 10, 12-14, 18, 19, 26-28, 32 and 33 are allowed.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims read upon, among other embodiments, human beings, which is not eligible subject matter for patenting.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-6, 8, 9, 11, 15-17, 22-25, 29-31, 34 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Verwaerde et al. (A, newly cited).

Claim 3 is drawn to a nucleic acid molecule comprising a sequence which hybridizes to SEQ ID NO:1. Claim 4 specifies that the hybridization is under stringent conditions. Claim 5 further specifies 6X ssc and 45 degrees C, as well as the recited wash conditions. Claim 6 is drawn to a nucleic acid molecule which exhibits the activity of the sod-3 promoter, which molecule is selected from: one with 90% or more identity to SEQ ID NO:1; a fragment of said one with 90% or more identity to SEQ ID NO:1; a fragment of SEQ ID NO:1; or a derivative of one of these. Claims 8 and 9 each specify one of the options in claim 6. Claim 11 is drawn to a nucleic acid comprising the molecule of claim 3 and a reporter gene. Claim 15 is drawn to a vector comprising the molecule of claim 3, which vector is specified to comprise DNA in claim 16, further specified in claim 17 that the DNA is linked to regulatory elements to cause expression of the reporter gene. Claim 22 is drawn to a transgenic host cell comprising the nucleic acid of claim 3, which cell is specified as a nematode cell in claim 23. Claim 24 is drawn to a transgenic host comprising the cell of claim 22, specified in claim 25 as a nematode. Claim 29 is drawn to contacting a transgenic C. elegans, which comprises the nucleic acid of claim 3, with at least one compound, measuring reporter gene activity with and without said compound, and comparing, thus to select a modulating compound. Claim 30 further specifies that the C. elegans are larvae. Claim 31 specifies that at least one reference compound be used. Claim 34 is drawn to a method of identifying modulators of the DAF-2/IR pathway comprising contacting a transgenic C. elegans larvae, which comprises the nucleic acid of claim 3, with at least one compound, measuring reporter gene activity with and without said compound, and comparing,

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thus to select a modulating compound. Claim 35 further specifies that at least one reference compound be used.

Verwaerde et al. teaches, e.g., in SEQ ID NOS:5 or 6 a nucleic acid molecule with high identity to SEQ ID NO:1 of the instant application. SEQ ID NO:5 of Verwaerde et al. matches all the bases of instant SEQ ID NO:1 from 156 to 1098, but also has 51 bases in addition inserted within instant SEQ ID NO:1. As such, the molecule of Verwaerde et al. would hybridize to that of SEQ ID NO:1 under stringent conditions and remain bound under the wash conditions of claim 5. Also, it would be a derivative in that one could alter SEQ ID NO:1 to produce SEQ ID NO:5 of Verwaerde et al. Two plasmids are taught, pGQ3 and pGQ4, are SEQ ID NOS:5 and 6, respectively, comprising the sod-3 promoter and coding region driving green fluorescent protein or luciferase, respectively, as a reporter gene. Example 2 of Verwaerde et al. teaches the construction of transgenic Caenorhabditis elegans cells comprising the plasmids described in the reference and the use of those cells to produce transgenic C. elegans. It is taught at paragraphs [0011]-[0038] and [0080] that the transgenic nematodes could be used in an assay for the effects of a compound on the reporter gene. In particular, [0026]-[0032] teach providing the worms with a promoter driving a marker (reporter) gene, exposing the worms to an exogenous factor, and detecting the reporter gene. Paragraph [0080] teaches the use of a reference compound. Paragraph [0038], for example, teaches using L1 larvae in such a method. With respect to claims 34 and 35, a modulator of sod-3 inherently would have been a modulator of the DAF-2/IR pathway.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-9, 11, 15-17, 22-25, 29-31, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification sets forth SEQ ID NO:1. However, the instant claims are drawn to a nucleic acid sequence that hybridizes to SEQ ID NO:1, or functional nucleic acids with 90% identity thereto, or a functional fragment thereof, or vector, cells, hosts or methods which make use thereof. However, neither the specification nor the prior art teaches which region or regions of the promoter are required for function, and there are no theories or formulae in the prior art that would have permitted one of skill to have known a priori which embodiments found within the structural limitations of the claims would have retained the specified activity. In the absence of such a structure-function relationship, one of skill would not have recognized that Applicants were in possession of the full scope of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
17 January 2007



JAMES KETTER
PRIMARY EXAMINER